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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,017	01/10/2001	Olav Lanes	U 013209-3	8104

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/758,017	Applicant(s) LANES ET AL.	
	Examiner Elizabeth Slobodyansky, PhD	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-38 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2003 has been entered.

The amendment filed December 2, 2003 amending the specification to correct references to the sequence identifiers, canceling claims 17-29 and adding claims 30-41 has been entered.

Claims 30-41 are pending.

Election/Restriction

Newly submitted claims 39 and 40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: invention of claims 30-38 and 41 and invention of claims 39-40 are related as a product and a process of use. These two inventions are restricted for the reasons given in the Restriction requirement mailed July 9, 2002. Claims 39-40 correspond to invention of Group IV, claims 15-16.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

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prosecution on the merits. Accordingly, claims 39-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 30-38 and 41 are under consideration.

Specification

The disclosure is objected to because of the following: It recites "one-letter code amino acid sequences for cUNG1 and cUNG2" (page 27, second full paragraph). While the original Sequence Listing filed January 10, 2001 used one-letter code, the current Sequence listing filed March 10, 2003 uses three-letter code.

The specification recites "Closer description of the figures" (page 4, line 30). It is customary to use the heading "Brief Description of the figures".

The Sequence Listing filed March 10, 2003 contains 22 sequence compared with 19 sequences in the Sequence Listing filed January 29, 2002. Furthermore, the same sequence identifier denotes different sequences in each Sequence listing (see, for example, SEQ ID NOs: 5, 6, etc). However, no amendment to the specification to reflect the changes in the Sequence Listing has been done.

Clarification and correction are required.

Claim Objections

Claims 30, 31 and 38 are objected to because of the following informalities: claim 30 recites "from amino acid 82 to 301" where it appears "amino acid 82 to amino acid 301" is intended. Claim 31 recites "from amino acid 1 to 81" where it appears "amino acid 1 to amino acid 81" is intended.

Claims 31 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 depends from claim 30. Claim 30 is drawn to an enzyme with uracil –DNA glycosylase activity having an amino acid sequence from amino acid 82 to amino acid 301 of SEQ ID NO: 2. Claim 31 is drawn to "the enzyme of claim 30 with a subcellular localization signal attached to the N-terminal". Said "subcellular localization signal" or any addition to the sequence consisting of residues 82-301 of SEQ ID NO:2 is not encompassed by claim 30.

Claim 38 recites "the enzyme of claim 30 further comprising a detectable label". Amending the claim to recite "an enzyme having uracil-DNA glycosylase activity comprising the enzyme of claim 30 and a detectable label", for example, is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 30 recites a functional fragment of a fragment consisting of residues 82-301 of SEQ ID NO:2 retaining uracil-DNA glycosylase activity.

While the specification discloses that fragment consisting of residues 82-301 of SEQ ID NO:2 has a uracil-DNA glycosylase activity (specification , page 24), the examiner is unable to locate adequate support in the specification for a fragment of the fragment. Thus there is no indication that a fragment of the 82-301 fragment was within the scope of the invention as conceived by Applicants at the time the application was filed.

Claim 31 recites "the subcellular localization signal is as set for the in SEQ ID NO:2 from amino acid 1 to 81 or a functional part thereof". Applicants indicate support for claim 31 on page 24, line 13 (Remarks of December 2, 2003, page 5). While the specification teaches that "74 and 81 of the N-terminal amino acids were removed, respectively" (page 24, line 13), the examiner is unable to locate adequate support in the specification for any functional fragment of the fragment consisting of residues 1-81 of SEQ ID NO:2. Thus there is no indication that a fragment of the 1-81 fragment with a

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possible exception of 1-74 fragment was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites "enzyme is completely inactivated when heated above about 60⁰ C". The use of "above" and "about" in one term is confusing because "above" means "60⁰ and above" but "about" encompasses below 60⁰ as well. Furthermore, "above 60⁰ C" can be any temperature and ultimately any enzyme is inactivated "above 60⁰ C". In addition, inactivation depends on conditions such as time and pH, for example. Without knowing said conditions the metes and bounds of the term are unascertainable. Finally, claim 30 is drawn to a single enzyme or a fragment thereof retaining its enzymatic activity. While Applicants are not prevented from the recitation of the properties, the properties recited in claim 30 are inherent to the enzyme.

Claims 33-37 depend from claim 30 and recite the source of the enzyme. Since claim 30 is drawn to a single enzyme it is unclear how claims 33-37 limit the scope of claim 30.

Claim 32 is confusing because the function is an inherent property of a peptide. Therefore, a fragment consisting of residues 1-81 of SEQ ID NO:2 is either a nuclear or a mitochondrial localization signal.

Claim 41 is drawn to "a composition for use in carry-over prevention". The intended use does not limit the scope of the claim. However, the term "carry-over prevention" is unclear without indicating prevention of carry-over of which compounds and in which reactions is encompassed.

Claims 31 and 38 are rejected as dependent from claim 30.

Response to Arguments

Applicant's arguments filed December 2, 2003 have been fully considered but they are not persuasive.

Applicants argue that the statement "absent the N-terminal sequences "The resulting proteins [UNG1 and UNG2] are identical and encompass the catalytic domain" cited from the Office action mailed June 2, 2003 "is correct" (Remarks of December 2, 2003, page 6). The examiner's statement was based on the comparison of SEQ ID NO: 2 and SEQ ID NO: 4 as they were presented in the Sequence Listing filed January 29, 2003. In said Sequence Listing, SEQ ID NO:2 and SEQ ID NO:4 differ at several positions comprising positions 197-199, for example. At the time the search was done

and the Office action was written, the examiner's statement was correct. Applicants have changed SEQ ID NO:4 in the Sequence Listing filed March 10, 2003. The changes comprise changes at least at positions 197-199. Applicants did not indicate and explain said changes in Remarks of March 10, 2003 and did not make changes to the specification, as noted *supra*. The examiner notes that said changes may have support in the specification and the Sequence Listing filed January 10, 2001. It appears that the Sequence Listing filed January 29, 2002 contained incorrect SEQ ID NO:4. However, Applicants should clarify the record.

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lanes et al. Comparative Biochemistry and physiology Part B (November 2000), Vol. 127, pages 399-410. Said article describes purification and characterization of a uracil-DNA glycosylase of the instant invention. It is not considered the art for the instant invention because Applicants disclose the invention in foreign priority applications written in English.

Lanes et al. (2002) Extremophiles, Vol. 6, pages 73-86 is a post-filing reference by the inventors' Group disclosing the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

February 27, 2004